

REMARKS/ARGUMENTS

Claims 9 to 11 and 19 to 21 have been amended to delete the references to analogues and derivatives of the recited macromolecules.

Claims 39 and 40 have been cancelled.

Claim 42 has been reformatted as a method claim, for consistency with claim 26 on which it depends.

Response to Sections 2 to 9 – 35 U.S.C. 112, 2nd & 35 U.S.C. 112, 1st

The Examiner objects to the references to "analogues" and "derivatives" of certain macromolecules in claims 9 to 11 and 19 to 21. These references have been deleted and so the objection no longer applies.

Response to Sections 10 to 18 – 35 U.S.C. 103

The Examiner objects to all claims, asserting that it would have been obvious to a skilled person to modify a bicarbonate composition of the type described by New in US 5,853,748 ('748) by adding propyl gallate (PG) or butylated hydroxy anisole (BHA), in view of US 5,206,219 ('219). It is argued that the skilled person would have been motivated to take this step in order to help preserve the pharmaceutical composition (section 16 of the Office Action). With respect, the Applicant disagrees.

The Examiner is referred to the attached Declaration signed by the inventor. As is explained in the Declaration (see sections 2 to 9), '748 describes bicarbonate compositions, the whole point of which is to form an aqueous solution during use. '219, on the other hand, teaches the use of a microemulsion containing fatty globules. Thus, it is simply not credible to suggest that a skilled person wishing to help preserve the '748 bicarbonate composition would have sought the answer in '219. Rather, as noted in sections 10 and 11 of the Declaration, the skilled person would have considered adding a well-known water-soluble preservative, such as vitamin C, sodium metabisuphite or malic acid.

In any case, no skilled person would have contemplated adding PG or BHA to the bicarbonate compositions of '748. As is explained in the Declaration (see sections 12 to 14), PG and BHA have low solubility in water. A copy of the textbook extract mentioned in section 12

of the Declaration is attached for ease of reference. The skilled person would have known that PG or BHA would be likely to prejudice the formation of an aqueous solution (which is the whole point of the bicarbonate '748 composition). As has already been confirmed in the Declaration filed on this case on July 31, 2009, that is in fact what happens – a turbid dispersion results. In other words, adding PG or BHA stops the '748 bicarbonate compositions from working.

Finally, as noted in section 15 of the Declaration, even if the skilled person had been shown document '219, they would still not have been motivated to add PG or BHA to the '748 bicarbonate composition. That is because '219 simply confirms that these additives are only suitable for use with oil or fat.

In view of the above comments, the Examiner's objection should be withdrawn.

Response to Sections 19 and 20 – 37 CFR 1.75(c)

The Examiner objects to claims 40 and 42 because they refer to compositions *per se*, but are dependent on claim 26, which is a method claim. Claim 40 has now been cancelled. Claim 42 has been revised to adopt a method format for consistency with claim 26. Accordingly, the objection to these claims no longer applies.

Response to Sections 21 to 24 – 35 U.S.C. 112, 1st

The Examiner objects to the reference to "at least 66 mg" of bile acid in claims 39 and 40. These two claims have now been cancelled and so this objection no longer applies.

Favorable reconsideration of this application is respectfully requested. Should the examiner require further information, please contact the undersigned.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



Arthur R. Crawford
Reg. No. 25,327

ARC:eaw
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100